



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Prospective Grant of an Exclusive License: The Development of an Anti-GPC3 Chimeric Antigen Receptor (CAR) based on HN3 for the Treatment of Human Cancers.

**AGENCY:** NATIONAL INSTITUTES OF HEALTH, PUBLIC HEALTH SERVICE, HHS

**ACTION:** Notice

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part

404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human

Services, is contemplating the grant of an exclusive license to practice the inventions embodied in:

Intellectual Property:

U.S. Provisional Patent Application 61/477,020 entitled “Human Monoclonal Antibody Specific for

Glypican-3 And Use Thereof” [HHS Ref. E-130-2011/0-US-01], PCT Patent Application

PCT/US2012/034186 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof”

[HHS Ref. E-130-2011/0-PCT-02], Chinese Patent Application 201280029201.3 entitled “Human

Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011/0-CN-03],

European Patent 2699603 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use

Thereof” [HHS Ref. E-130-2011/0-EP-04], and validated in France, Germany and the United Kingdom,

United States Patent 9,206,257 entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use

Thereof” [HHS Ref. E-130-2011/0-US-05], United States Patent Application 14/837,903 entitled “Human

Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011/0-US-06],

European Patent Application 15188264.4 entitled “Human Monoclonal Antibodies Specific for Glypican-3

And Use Thereof” [HHS Ref. E-130-2011/0-EP-07], United States Patent Application 15/090,873 entitled

“Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-2011/0-US-

12], Chinese Patent Application 201610290837.3 entitled “Human Monoclonal Antibodies Specific for

Glypican-3 And Use Thereof” [HHS Ref. E-130-2011/0-CN-13], European Patent Application 16166924.7

entitled “Human Monoclonal Antibodies Specific for Glypican-3 And Use Thereof” [HHS Ref. E-130-

2011/0-EP-14], and all continuing U.S. and foreign patents/patent applications for the technology family, to Lentigen Technology, Inc.

The patent rights to these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive licensed territory may be the United States, Australia, Canada, the European Union, Russia, China, Hong Kong, Japan, Taiwan, South Korea and Singapore, and the field of use may be limited to: “The development of a glypican-3 (GPC3) chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) primary human lymphocytes (T cells or NK cells) transfected with a lentiviral or retroviral vector, wherein the vector expresses a CAR having 1) a single antigen specificity and 2) comprising at least: a) the complementary determining region (CDR) sequences of the anti-GPC3 antibody known as HN3; and b) a T cell signaling domain; for the prophylaxis and treatment of GPC3-expressing cancers.”

**DATES:** Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

**ADDRESSEES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, National Cancer Institute, 9609 Medical Center Drive, Rm 1-E530 MSC9702, Rockville, MD 20850-9702, E-mail: david.lambertson@nih.gov.

**SUPPLEMENTARY INFORMATION:** This invention concerns an anti-GPC3 (Glypican-3) chimeric antigen receptor (CAR) and methods of using the CAR for the treatment of GPC3-expressing cancers. GPC3 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, particularly liver cancers such as hepatocellular carcinoma (HCC). The anti-GPC3 CARs of this technology contain (1) antigen recognition sequences that bind specifically to GPC3 and (2) signaling domains that can activate the cytotoxic functions of a T cell. The anti-GPC3 CAR can be transduced into T cells that are harvested from a donor, followed by (a) selection and expansion of the T cells expressing the anti-GPC3 CAR, and (b) reintroduction of the T cells into the patient. Once the anti-GPC3 CAR-expressing T cells are reintroduced into the patient, the T cells can selectively bind to GPC3-expressing cancer cells through its

antigen recognition sequences, thereby activating the T cell through its signaling domains to selectively kill the cancer cells. Through this mechanism of action, the selectivity of the a CAR allows the T cells to kill cancer cells while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Date: June 3, 2016

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Technology Transfer Center

National Cancer Institute

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